Drug

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0516]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions relating to the regulations which state that protocols for samples of biological products must be submitted to the agency.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.

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1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques when appropriate, and other forms of information technology.

Request for Samples and Protocols (OMB Control Number 0910–0206)—Extension

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), FDA may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests before marketing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: § 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen), § 660.36 (21 CFR 660.36) (Reagent Red Blood Cells), and § 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen).

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by the Center for Biologics Evaluation and Research (CBER). After official release is no longer required, one sample along with a protocol is required to be submitted at an interval

of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires a protocol contain information including, but not limited to, manufacturing records, test records, and test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to FDA at the time of initial distribution of each lot.

Section 660.46(a) provides requirements for the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological

products (e.g., Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of any licensed biological product. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced above. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. There are an estimated 329 manufacturers of licensed biological products, however, based on information obtained from FDA's database system, approximately 83 manufacturers submitted samples and protocols in fiscal year 1999 and 2000, under the regulations cited previously. FDA estimates that approximately 76 manufacturers submitted protocols under § 610.2 and 7 manufacturers submitted protocols under the regulations for the specific products.

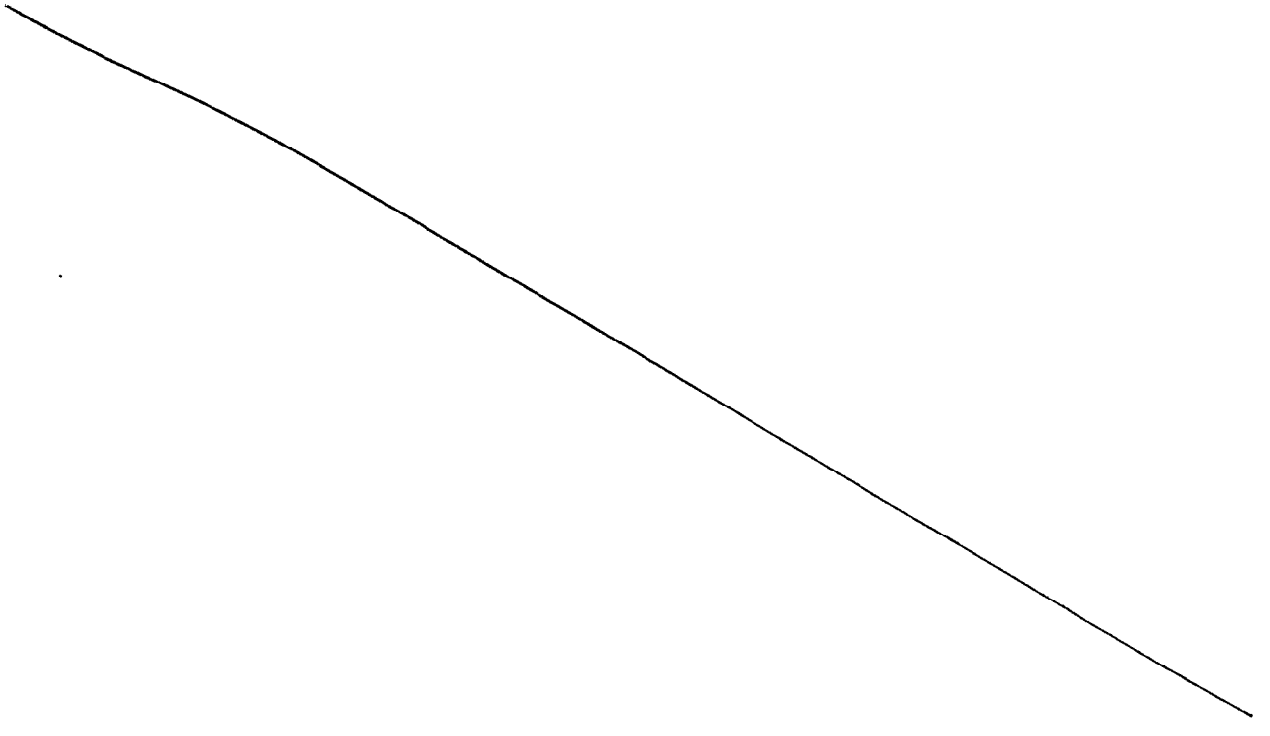
The total annual responses are based on the annual average of FDA's final actions completed in fiscal year 1999 and 2000, which totaled 6,747, for the various submission requirements of samples and protocols for biological

products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) because more information is generally required to be submitted in the protocol than under § 610.2. FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
610.2	76	86.5	6,574	3	19,722
660.6(b)	4	28.5	114	5	570
660 36(a)(2) and (b)	1	1	1	6	6
660.46(b)	2	29	58	5	290
Total	83		6,747		20,588

[1] There are no capital costs or operating and maintenance costs associated with this collection



Dated: 12-19-02
December 19, 2002.

Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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